

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

PRONOVA BIOPHARMA NORGE AS,

Plaintiff,

v.

APOTEX CORP. and APOTEX INC.,

Defendants.

C.A. No. 1:11-cv-12-SLR

**JURY TRIAL DEMANDED**

**ANSWER, DEFENSES, COUNTERCLAIMS AND JURY DEMAND  
OF DEFENDANTS APOTEX INC. AND APOTEX CORP.**

Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") respond and answer as follows. Every allegation not expressly admitted is denied.

**THE PARTIES**

1. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1, and therefore denies these allegations.

2. Apotex admits that Apotex Corp. is a Delaware corporation with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Apotex denies the remaining allegations of Paragraph 2. Apotex further denies that Apotex Corp. is a proper party to this suit, and also denies that this Court has subject matter jurisdiction for any claims asserted against Apotex Corp.

3. Apotex admits that Apotex Inc. is a corporation operating and existing solely under the laws of Canada with its only places of business located in Canada, including at 150

Signet Drive, Weston, Ontario M9L 1T9, Canada. Apotex denies the remaining allegations of Paragraph 3.

**NATURE OF THE ACTION**

4. Paragraph 4 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits that this action purports to allege patent infringement, and that Apotex Inc. filed with the U.S. Food and Drug Administration (“FDA”) an Abbreviated New Drug Application (“ANDA”) seeking FDA approval for Omega-3-Acid Ethyl Esters Capsules, 1g. Apotex denies the remaining allegations of Paragraph 4.

**JURISDICTION AND VENUE**

5. Paragraph 5 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits that subject matter jurisdiction is proper solely for claims directed against Apotex Inc. under 35 U.S.C. § 271(e)(2)(A) only. Apotex denies that Apotex Corp. is a proper party to this suit, denies that subject matter jurisdiction is proper for any claims asserted against Apotex Corp., and further denies subject matter jurisdiction for any claims asserted under 35 U.S.C. § 271(a), (b), (c) or (g). Apotex denies the remaining allegations of Paragraph 5.

6. Paragraph 6 contains legal conclusions to which no answer is required. To the extent an answer is required, and to conserve the resources of the parties and this Court, Apotex Corp. does not contest personal jurisdiction in this judicial district solely for the limited purposes of this action only. Apotex denies that Apotex Corp. is a proper party to this suit. Apotex denies the remaining allegations of Paragraph 6.

7. Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 7. Further answering, to

conserve the resources of the parties and this Court, Apotex Inc. does not contest personal jurisdiction in this judicial district solely for the limited purposes of this action only.

8. Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 8. Further answering, to conserve the resources of the parties and this Court, Apotex does not contest venue in this judicial district solely for the limited purposes of this action only.

**FIRST COUNT FOR PATENT INFRINGEMENT**

9. Apotex admits that Exhibit A to the Complaint purports to be a copy of U.S. Patent No. 7,732,488 (“the ‘488 patent”), that the cover page of the ‘488 patent indicates that it purportedly issued on or about June 8, 2010, and that it is entitled “Pharmaceutical Composition Comprising Low Concentrates of Environmental Pollutants.” Apotex denies that the ‘488 patent was lawfully issued. Apotex denies the remaining allegations of Paragraph 9.

10. Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits that the electronic assignment records of the U.S. Patent and Trademark Office (“PTO”) appear to identify “Pronova Biocare AS” at Reel 016754, Frame 0279, as the purported assignee of the ‘488 patent. Apotex denies the remaining allegations of Paragraph 10.

11. Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 11.

12. Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex denies the allegations of Paragraph 12.

13. Apotex admits that the electronic version of FDA’s publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as “the Orange Book”),

lists the '488 patent in connection with approved New Drug Application ("NDA") No. 21-654, and that, according to the Orange Book, NDA No. 21-654 was approved on or about November 10, 2004. Apotex denies the remaining allegations of Paragraph 13.

14. Apotex admits that the Orange Book identifies "Lovaza" as the proprietary name for the drug product approved under NDA No. 21-654. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 14, and therefore denies these allegations.

15. Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Apotex admits that Apotex Inc. filed an ANDA with FDA for Omega-3-Acid Ethyl Esters Capsules, 1g. Apotex denies that Apotex Corp. submitted such an ANDA, denies that Apotex Corp. is a proper party to this suit, and also denies that this Court has subject matter jurisdiction for any claims asserted against Apotex Corp. Apotex denies the remaining allegations of Paragraph 15.

16. Apotex admits that Apotex Inc. filed an ANDA with FDA for Omega-3-Acid Ethyl Esters Capsules, 1g. Apotex denies that Apotex Corp. submitted such an ANDA, denies that Apotex Corp. is a proper party to this suit, and also denies that this Court has subject matter jurisdiction for any claims asserted against Apotex Corp. Apotex denies the remaining allegations of Paragraph 16.

17. Apotex admits that, in a letter dated November 23, 2010, from Apotex Inc.'s outside counsel, RAKOCZY MOLINO MAZZOCHI SIWIK LLP, Apotex Inc. provided the requisite notice of its ANDA to, among others, Pronova Biopharma Norge AS ("Pronova"); and that Apotex Inc.'s notice satisfies all statutory and regulatory requirements. Apotex denies the remaining allegations of Paragraph 17. Apotex further denies that Apotex Corp. is a proper party

to this suit, and also denies that this Court has subject matter jurisdiction for any claims asserted against Apotex Corp.

18. Apotex admits that Apotex Inc.'s notice letter provides that Apotex Inc. filed an ANDA with FDA for Omega-3-Acid Ethyl Esters Capsules, 1g. Apotex denies the remaining allegations of Paragraph 18. Apotex further denies that Apotex Corp. is a proper party to this suit, and also denies that this Court has subject matter jurisdiction for any claims asserted against Apotex Corp.

19. Denied.

20. Denied.

21. Denied.

\* \* \*

#### SEPARATE DEFENSES

Without undertaking any of the burdens imposed by law on Plaintiff, and without admitting any of the allegations in the complaint not otherwise admitted, defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") assert the following separate defenses:

##### First Defense

The manufacture, use, offer for sale, or importation of the Omega-3-Acid Ethyl Esters Capsules, 1g, product that is the subject of Apotex Inc.'s ANDA has not infringed, does not infringe, and would not, if made, imported or marketed, infringe any valid and/or enforceable claim of U.S. Patent No. 7,732,488 ("the '488 patent").

##### Second Defense

Apotex has not induced or contributed to, and will not induce or contribute to, infringement of any valid and/or enforceable claim of the '488 patent.

**Third Defense**

Pronova is barred by prosecution history estoppel from presenting an interpretation of the claims of the '488 patent necessary to find infringement.

**Fourth Defense**

The claims of the '488 patent are invalid for failure to satisfy one or more conditions for patentability set forth in Title 35 of the United States Code.

**Fifth Defense**

This Court lacks subject matter jurisdiction over Pronova's claims against Apotex Corp.

**Sixth Defense**

Apotex Corp. is not a proper party to this suit.

**Seventh Defense**

The Court lacks subject matter jurisdiction for any claims asserted under 35 U.S.C. § 271(a), (b), (c) or (g).

**Eighth Defense**

For the reasons stated with particularity in Apotex's counterclaims, which allegations are incorporated by reference herein, the '488 patent is unenforceable due to inequitable conduct before the United States Patent and Trademark Office.

**Ninth Defense**

Any additional defenses or counterclaims that discovery may reveal.

\* \* \*

Apotex denies every allegation not expressly admitted herein. Apotex further denies that Pronova is entitled to any of the relief requested, or any relief whatsoever. Apotex

demands judgment dismissing Pronova's complaint with prejudice, awarding Apotex attorney fees and costs incurred in defending this action under 35 U.S.C. § 285, and granting such further relief as this Court may deem just.

### **COUNTERCLAIMS**

For their Counterclaims against Pronova BioPharma Norge AS, Apotex Inc. and Apotex Corp. (collectively "Apotex") allege as follows:

#### **Parties**

1. On information and belief, Pronova BioPharma Norge AS ("Pronova") purports to be a corporation organized and existing under the laws of Norway, having its principal place of business at Vollsveien 6, 1366 Lysaker, Baerum, Norway.

2. Apotex Inc. is a corporation operating and existing solely under the laws of Canada with its only places of business located in Canada, including at 150 Signet Drive, Weston, Ontario M9L 1T9, Canada.

3. Apotex Corp. is a corporation organized under the laws of the State of Delaware, having a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

#### **Jurisdiction and Venue**

4. These Counterclaims arise under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

6. This Court has personal jurisdiction over Plaintiff/Counterclaim-Defendant Pronova because, *inter alia*, Pronova has availed itself of the rights and privileges of this forum by suing Apotex Inc. and Apotex Corp. in this District, and, on information and belief, because Plaintiff/Counterclaim-Defendant Pronova conducts substantial business in, and has regular systematic contact with, this District.

**Patent-in-Suit**

7. On or about June 8, 2010, the U.S. Patent and Trademark Office (“PTO”) issued U.S. Patent No. 7,732,488 (“the ’488 patent”), entitled “Pharmaceutical Composition Comprising Low Concentrations of Environmental Pollutants,” to Harald Breivik and Olav Thorstad. A true and correct copy of the ’488 patent is attached hereto as **Exhibit A**.

8. Pronova purports and claims to own, and/or to have the right to enforce, the ’488 patent.

9. On or about January 5, 2011, Pronova sued Apotex Inc. and Apotex Corp. in this District alleging infringement of the ’488 patent under 35 U.S.C. § 271(e)(2)(A).

**Count I**  
**(Declaratory Judgment of Non-Infringement of the ’488 Patent)**

10. Apotex realleges and incorporates by reference the allegations of paragraphs 1-9.

11. A present, genuine, and justiciable controversy exists between Pronova and Apotex regarding, *inter alia*, non-infringement of the ’488 patent.

12. The manufacture, use, offer for sale, or sale of Apotex Inc.'s Omega-3-Acid Ethyl Esters Capsules (1g) product described in Apotex Inc.'s ANDA would not infringe any valid and/or enforceable claim of the '488 patent.

13. Apotex is entitled to a declaration that the manufacture, use, offer for sale, or sale of its Omega-3-Acid Ethyl Esters Capsules (1g) product described in Apotex Inc.'s ANDA would not infringe any valid and/or enforceable claim of the '488 patent.

**Count II**  
**(Declaratory Judgment of Invalidity of the '488 Patent)**

14. Apotex realleges and incorporates by reference the allegations of paragraphs 1-13.

15. A present, genuine, and justiciable controversy exists between Pronova and Apotex regarding, *inter alia*, the invalidity of the '488 patent.

16. The '488 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

17. Apotex is entitled to a declaration that the '488 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

**Count III**  
**(Declaratory Judgment of Unenforceability of the '488 Patent)**

18. Apotex realleges and incorporates by reference the allegations of paragraphs 1-17.

19. The '488 patent is unenforceable by reason of the failure of Pronova and/or the Inventors and/or others involved in the prosecution of the application from which the '488 patent issued (collectively, "Applicants") to fulfill their duties of candor under 37 C.F.R. § 1.56.

20. On or about March 26, 1996, the U.S. Patent and Trademark Office ("PTO") issued U.S. Patent No. 5,502,077 ("the '077 patent"), entitled "Fatty Acid Composition," to Harald Breivik, Bernt Borretzen, Knut H. Dahl, Hans E. Krokan, and Kaare H. Bonaa.

21. On or about August 12, 1997, the PTO issued U.S. Patent No. 5,656,667 (“the ’667 patent”), entitled “Fatty Acid Composition,” to Harald Breivik, Bernt Børretzen, Knut Helkås Dahl, Hans Einar Krokan, and Kaare Harald Bønaa.

22. On or about March 16, 2010, the PTO issued U.S. Patent No. 7,678,930 (“the ’930 patent”), entitled “Process for Decreasing the Amount of Cholesterol in a Marine Oil Using a Volatile Working Fluid,” to Sverre Sondbø and Olav Thorstad.

23. On or about May 18, 2010, the PTO issued U.S. Patent No. 7,718,698 (“the ’698 patent”), entitled “Process for Decreasing Environmental Pollutants in an Oil or a Fat,” to Harald Breivik and Olav Thorstad.

24. The ’698 patent is a continuation of the ’488 patent. The ’698, ’488, and ’930 patents each claim priority to the same foreign application (SE 0202188), which was filed on July 11, 2002.

25. Pronova purports and claims to own, and/or to have the right to enforce, the ’488 patent, the ’077 patent, the ’667 patent, the ’930 patent, and the ’698 patent.

**A. The ’488 Patent Is Unenforceable (Failure to Disclose Related Litigations)**

26. On March 20, 2009, Apotex mailed to Pronova, as assignee of the ’077 and ’667 patents, a Notice of Certification relating to the ’077 and ’667 patents. Pronova received the Notice of Certification on or about March 24, 2009. The Notice of Certification provided a statement of the factual and legal basis for Apotex’s Paragraph IV Certification that the ’667 and ’077 patents are invalid, unenforceable and/or not infringed by Apotex’s ANDA seeking FDA approval to engage in the commercial manufacture, use, or sale of pharmaceutical products containing omega-3-acid ethyl esters.

27. On April 29, 2009, Pronova filed its Complaint in the co-pending infringement suit against Apotex, *Pronova BioPharma Norge AS v. Apotex Corp. and Apotex Inc.*, Case No. 1:09-cv-304-SLR-MPT (“the Related Litigation”), alleging infringement of the ’077 and ’667 patents.

28. On June 29, 2009, Apotex filed an Answer in response to the Complaint, asserting the affirmative defenses of invalidity, non-infringement, and unenforceability of the ’077 and ’667 patents. Apotex also filed declaratory judgment counterclaims, alleging the invalidity, non-infringement, and unenforceability of the ’077 and ’667 patents.

29. Pronova contemporaneously filed infringement suits asserting the ’077 and ’667 patents against two other generic manufacturers seeking FDA approval to engage in the commercial manufacture, use, or sale of pharmaceutical products containing omega-3-acid ethyl esters.

30. On or about April 7, 2010, Pronova filed its Motion for Leave to File First Amended Complaint to add a claim against Apotex Inc. and Apotex Corp. for infringement of the ’930 patent under 35 U.S.C. § 271(g).

31. On or about June 17, 2010, Pronova filed its Motion for Leave to File Second Amended Complaint to add a claim against Apotex Inc. and Apotex Corp. for infringement of the ’698 patent under 35 U.S.C. § 271(g).

32. On information and belief, counsel for Pronova in the prosecution of the applications that issued as the ’488 patent were familiar with the issues in the Related Litigation.

33. Finnegan, Henderson, Farabow, Garrett and Dunner, L.L.P. (“Finnegan”) acted as patent counsel for Pronova in the prosecution of the applications that issued as the ’488, ’930 and ’698 patents. The submission by Pronova on February 28, 2007, to the PTO of a Revocation of

Power of Attorney and Grant of New Power of Attorney authorized Finnegan to represent Pronova in front of the PTO for the prosecution of the applications that issued as the '488, '930 and '698 patents. Thereafter, Finnegan acted as counsel for Pronova in the prosecution of the applications that issued as the '488, '930 and '698 patents.

34. Finnegan has also acted as lead counsel for Pronova with respect to the Related Litigation since before it commenced with the filing of Pronova's Complaint on the '077 and '667 patents.

35. Finnegan was familiar with the prosecution of the '488, '930 and '698 patents as well as with the Related Litigation.

36. On information and belief, Anthony Tridico, an attorney with Finnegan, was familiar with the prosecution of the '488, '698 and '930 patents as well as with the Related Litigation.

37. Anthony Tridico participated in the prosecution of the application that issued as the '488 patent, signing papers responding to Office Actions, filing Information Disclosure Statements, and meeting with the Patent Examiner on behalf of Pronova.

38. Anthony Tridico also signed the papers submitted to the PTO when the application that later issued as the '698 patent was filed with the PTO on May 1, 2008.

39. Anthony Tridico is also a signatory to Pronova's Complaint against Apotex in both the present litigation and the Related Litigation. Anthony Tridico was admitted to the Court pro hac vice in the Related Litigation on or about August 17, 2009.

40. The '488 patent relates to the subject matter of the Related Litigation. The '488 patent issued from the parent application of the '698 patent and shares the same disclosure.

Pronova has caused the '488 patent to be listed in the Orange Book for Lovaza, along with the '077 and '667 patents-in-suit in the Related Litigation.

41. On information and belief, Finnegan, whose attorneys had a duty of candor under 37 C.F.R. § 1.56, withheld the fact of the existence of the Related Litigation with an intent to deceive the PTO into granting the '488 patent.

42. Despite the clear materiality of the Related Litigation against Apotex (and other ANDA applicants), Pronova did not disclose the Related Litigation to the PTO.

43. Despite the clear materiality of the Related Litigation against Apotex (and other ANDA applicants), Finnegan did not disclose the Related Litigation to the PTO.

44. The Related Litigation was material to the prosecution of the '488 patent because a reasonable examiner would want to know of the existence of a pending litigation concerning a related patent, including any material information arising from the litigation such as arguments concerning the prior art or allegations of inequitable conduct. *See U.S. PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2001.06(c)* (8th ed. 2001, 8th rev. 2010).

45. On information and belief, Pronova's failure to disclose the Related Litigation to the PTO was done with deceptive intent.

46. On information and belief, Finnegan's failure to disclose the Related Litigation to the PTO was done with deceptive intent.

47. Pronova's failure to disclose the Related Litigation to the PTO renders the '488 patent unenforceable due to Pronova's inequitable conduct.

48. Finnegan's failure to disclose the Related Litigation to the PTO renders the '488 patent unenforceable due to Finnegan's inequitable conduct.

49. As a result, the '488 patent is unenforceable due to inequitable conduct before the PTO.

50. Apotex is entitled to a declaration that the '488 patent is unenforceable due to inequitable conduct.

**B. The '488 Patent Is Unenforceable (EPAX Products)**

51. During the prosecution of the application that issued as the '488 patent, on or about March 12, 2007, Pronova and its counsel submitted to the PTO a "Supplemental Preliminary Amendment" disclosing the marine oil compositions comprising EPA ethyl ester and DHA ethyl ester called "EPAX" and asserting to the PTO that the EPAX products were not prior art.

52. Pronova and its counsel stated to the PTO that EPAX products were sold in the United States prior to the effective U.S. filing date of the '488 patent.

53. Pronova and its counsel stated to the PTO that the EPAX products do not fall within the scope of the claims of the application that issued as the '488 patent because the claims required "a pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia" and represented that the EPAX products were not therapeutically effective in treating hypertriglyceridaemia.

54. Pronova and its counsel asserted that the claimed invention was patentable because the EPAX products were not effective in reducing triglyceride levels.

55. Pronova and its counsel were nevertheless aware of multiple prior art references disclosing that several EPAX products were effective in lowering triglycerides.

56. Pronova and its counsel withheld these EPAX prior art references to the PTO during the prosecution of the '488 patent.

57. Upon information and belief, Pronova failed to disclose the EPAX prior art with the intent to mislead the PTO examiner as to the patentability of the claims sought.

58. Upon information and belief, Finnegan failed to disclose the contradictory prior art with the intent to mislead the PTO examiner as to the patentability of the claims sought.

59. Pronova's failure to disclose material prior art to the PTO with the intent to deceive renders the '488 patent unenforceable due to Pronova's inequitable conduct.

60. Finnegan's failure to disclose material prior art to the PTO with the intent to deceive renders the '488 patent unenforceable due to Finnegan's inequitable conduct.

### **C. The '488 Patent Is Unenforceable (NMFS)**

61. More than one year before the priority date for the '488 patent, the U.S. National Marine Fisheries Service ("NMFS") was producing a highly-concentrated omega-3 fish oil with reduced levels of environmental pollutants.

62. More than one year before the priority date for the '488 patent, the NMFS work was public.

63. On October 10, 2003, alleged inventor Harold Breivik signed a declaration stating that "I hereby declare that I believe I am the original, first and sole (if only one inventor is listed below) or joint (if more than one inventor is listed below) inventor of the subject matter which is claimed and for which a patent is sought." Breivik's inventorship declaration was false.

64. Breivik was aware of the NMFS process for forming a highly-concentrated omega-3 fish oil with reduced levels of environmental pollutants and in fact communicated with NMFS regarding improving their own concentrated ethyl ester product, which is purportedly the subject of the '488 patent.

65. Upon information and belief, Applicants, including at least Harald Breivik, failed to disclose the NMFS information with the intent to mislead the examiner as to the patentability of the claims sought.

66. Applicant's failure to disclose the NMFS information to the PTO with the intent to deceive renders the '488 patent unenforceable due to Applicant's inequitable conduct.

**REQUEST FOR RELIEF**

WHEREFORE, Apotex respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiff/Counterclaim-Defendant as follows:

- (a) declaring that the manufacture, sale, offer for sale, use or importation of the Omega-3-Acid Ethyl Esters Capsules (1g) product described in Apotex Inc.'s ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '488 patent;
- (b) declaring the claims of the '488 patent invalid;
- (c) declaring the '488 patent unenforceable as a result of inequitable conduct before the PTO;
- (d) ordering that Plaintiff's complaint be dismissed with prejudice and judgment entered in favor of Defendants;
- (e) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Defendants attorney fees, costs, and expenses in this action; and
- (f) awarding Defendants any further and additional relief as the Court deems just and proper.

**JURY DEMAND**

Apotex Inc. and Apotex Corp. demand a trial by jury as to all issues so triable.

Dated: January 26, 2011

Respectfully submitted,

PHILLIPS GOLDMAN & SPENCE, P.A.

*/s/ John C. Phillips, Jr.*

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